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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of : Itescu, S.

Application No. : 09/509,734 Group No.: 1644

Filed : June 14, 2000 Examiner: David A. Saunders.

For : METHOD FOR PREDICTING TRANSPLANT REJECTION

CERTIFICATE OF MAILING

I hereby certify that this paper is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on December 3, 2001.

Attorney Name Carmella L. Stephens Registration No. 41,328

Signature Carmella L. Stephens Date of Signature December 3, 2001

RESPONSE TO RESTRICTION REQUIREMENT

Assistant Commissioner for Patents
Washington, DC 20231

In response to the Restriction Requirement dated June 1, 2001, please consider the following remarks. The Examiner has stated that the claims of the present application contain five inventions, which he has divided into the following groups:

Group I, claims 1-7 and 19, drawn to assessing the risk of transplant rejection via detection of activated T-cells and IgG anti-HLA Class II antibodies;

Group II, claims 8-9 and 13-16 drawn to kits containing solid phase HLA antigens and a reagent for detecting IgG.;

GroupIII, Claim 10-11, drawn to kits containing complement and a denaturing agent;

Group IV, claim 12, drawn to kits containing cells and labeled anti-IgG; and

Group V, claim 17-18, drawn to methods of detecting and comparing anti-HLA antibody reactivity against B-cells versus T-cells.

According to the Examiner, the inventions listed as groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features.

According to the Examiner, the testing methods of Groups I and V involve different steps, *e.g.*, only Group II requires determining the ratio of anti-HLA reactivity to B-cells versus T-cells. In addition, the different groups involve the use of different reagents, *e.g.* only Group II requires use of DTT, and the claims of Group V can be conducted upon patients other than transplant patients, *e.g.*, multiple transfused patients or multiparous women. These methods thus do not have the same special technical feature to provide for unity of invention.

The Examiner alleges that the components of the kits of Groups II-IV bear no clear relationship to the methods of Groups I and V and thus do not provide for a single inventive concept. For example, the kids of Groups II and IV require provision of a means for detecting IgG antibody or a labeled IgG antibody, but use of such a reagent is not recited in the method of Groups I or V. The kit of Group III requires provision of complement and a denaturing agent; the method of Group I does not require use of a denaturing agent, and the method of Group V does not require use of complement. Further, even if it were considered that there is a nexus between the kits of Groups II-IV and the methods of Groups I and V, it is to be noted that if multiple products, process of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention of the claims (PCT Article

17(3)(a)). Therefore, at most, applicant could only consider the first recited method and first recited kit as constituting the main invention.

Further, the kits of Groups II-IV would have uses in conducting the methods other than those of Groups V and V. For example, they could be used in HLA typing to determine autoimmune disease associations. The kit of Group II could be used to conduct a complement fixation test or a Jerne plaque assay. In any case, the components of the kits of Groups II-IV are old and known not constitute a contribution by applicant over the prior art and thus cannot be considered as involving an inventive concept under PCT Rule 13.1.

The Examiner has required that Applicants restrict the prosecution of this application to one of the foregoing groups of claims.

In response, Applicants elect to pursue the claims of Group I in this application without prejudice to the prosecution of the subject matter of non-elected claims in other patent applications. Applicants make their election with traverse, on the grounds that the claimed testing methods of Group I and Group X are conceptually linked, and would not require separate searches.

Specifically, the testing methods encompassed by the claims of Group I and Group V both involve the use of a method for determining the presence of anti-HLA IgG antibodies with specificity for MHC class I or class II antigens (see, step (c) of claim 1). The methods of claim 17-19 merely encompass a specific method that may be utilized to determine the presence of anti-HLA IgG antibodies specific for class I or class II antigens.

The Examiner alleges that the methods involve different steps, i.e., determining the ratio of anti-HLA reactivity to B-cells versus T-cells, and the use of difference reagents, i.e.,

use of DTT. In this regard, the Examiner's attention is directed to p. 10, lines 19-25, of the specification which specifies that dithioerythritol treatment can be used to identify the presence of IgG alloantibodies (as required by step (c) of method claims 1-7 and the method of claims 17-19). Although step (c) of claims 1-7 is not limited to the use of DTT to determine the presence of circulating IgG anti-HLA class II antibodies, it is nevertheless a method that can be utilized for such a purpose.

Furthermore, Applicants maintain that contrary to the Examiner's contention the components of the kits of Groups II-IV do indeed bear a relationship to the methods of Groups I and V. The kits of Group II-IV comprise components that may be utilized to carry out the method steps of claims 1-7 and 17-19.

Accordingly, Applicants request that the restriction requirement be reconsidered.

The Commissioner is hereby authorized to charge payment of any fees associated with this communication to Deposit Account No. 02-4377. Two copies of this sheet are enclosed.

Respectfully submitted,

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